APR 2 1 2005

K050030

510k SUMMARY OF SAFETY AND EFFECTIVENESS

1. Trade (Proprietary) Name

Acticoat® Moisture Control Dressing

2. Common/Classification Name

Common name: Silver coated Antimicrobial Barrier Foam Dressing/Wound or Burn Dressing

Classification Name: KMF

3. Applicant's Name & Address

Smith & Nephew Inc
11775 Starkey Road,
PO Box 1970,
Largo, Florida,
FL 33779-1970

4. Device classification and Panel

A classification for wound/burn dressings has not been implemented. The device category is considered unclassified.

5. Predicate device

Acticoat® Foam Dressing (K000051)

K050030

6. Other similar devices

Allevyn® Hydrophillic Dressing (K963096) and Hydrasorb Sterile Dressing (K973260) are similar to the subject device with respect to materials and construction. Both of these similar dressings possess an absorbent polyurethane foam layer and polyurethane film lacking while are equivalent to the corresponding layers of the subject device, however, neither the Allevyn nor Hydrasorb dressings possess a wound contact layer with an antimicrobial silver coating.

6. Performance Standards

No applicable performance standards have been established under Sec. 514 of the FD&C Act.

7. Intended use and Device Description

The Acticoat Moisture Control dressing, an addition to the Acticoat® Dressing line of products is intended as an absorbent dressing which provides an effective barrier to bacterial penetration. Acticoat® Moisture Control Dressing is indicated for use in light to moderately exuding partial and full thickness wounds including decubitus ulcers, diabetic ulcers, 1st and 2nd degree burns, and donor sites. Acticoat® Moisture control may be used over debrided and partial thickness wounds.

The absorbent, antimicrobial barrier dressing consists of three layers. An outer blue polyurethane film layer, a central polyurethane foam layer and a nanocrystalline silver coated polyurethane film wound contact layer. The layers are heat laminated together to form a single dressing. The dressing can be cut to size and maintains its antimicrobial activity for up to 7 days.

The nanocrystalline silver layer is applied by a process known as physical vapor deposition which is identical manufacturing process approved for use in the manufacture of the predicate device Acticoat Foam (K000051). The same process is also approved as the method for

applying a silver coating for all other Acticoat brand dressings as described in the following cleared premarket notifications:

- Acticoat Dressings Foam (K000051)
- Acticoat Moisture Control (K010447)
- Acticoat 7 Dressing (K001519)
- Acticoat Alginate – Absorbent (K002896)
- Acticoat Primary – Burn (K99222)

8. Biocompatability

The biocompatibility of Acticoat Moisture Control has been demonstrated through appropriate *in vivo* and *in vitro* tests as well as previous tests on individual components. The product has been assessed in accordance with ANSI/AAMI/ISO 10993. The product does not introduce any additional safety risk over the predicate device Acticoat Foam (K000051)

9. Summary of Substantial Equivalence[1]

The labeled indications of the Acticoat Moisture Control Dressing are identical to those of the predicate device Acticoat Foam (K000051). The directions for use are equivalent to those of the predicate device Acticoat Foam (K000051). The design, materials and manufacturing methods of the dressings are comparable to those of the predicate dressing and do not raise any new issues of safety and effectiveness.

[1] Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or classification and is not to be interpreted as an admission or used as evidence in patent infringement litigation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2005

Mr. Terry C. McMahon
Manager, Regulatory Affairs- Devices
Smith and Nephew, Inc.
Wound Management
11775 Starkey Road
Largo, Florida 33773

Re: K050030
Trade/Device Name: Acticoat® Moisture Control Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 11, 2005
Received: April 12, 2005

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ACTICOAT® MOISTURE CONTROL DRESSING

510(k) Number:

Device Name: Acticoat® Moisture Control Dressing

Indications for Use:

The Acticoat® Moisture Control Dressing is indication for use in light to moderately exuding partial thickness wounds including decubitus ulcers, 1st and 2nd degree burns, and donor sites. Acticoat Moisture Control may be used over debrided and partial thickness wounds

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

X
Prescription (Per 21 CFR 801.109) OR ___ Over the Counter Use

(Optional Format 1-2-96)

...Action Sign-Off)
...vision of General, Restorative
...d Neurological Devices

K050030